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Date: October 29, 2003
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Our Ref. No.: PF-0169-2 CON
Your Ref. No.: 09/938,885
Page(s): 13 , including cover sheet

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I hereby certify that this paper is being facsimile transmitted to the attention of Examiner David S. Romeo, Group Art Unit 1647,
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Bandman et al.Title: LUNG GROWTH FACTOR VARIANTSerial No.: 09/938,885Filing Date: August 24, 2001Examiner: Romeo, D.Group Art Unit: 1647

Mail Stop: Non-Fee Amendment

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

FEE TRANSMITTAL SHEET

Sir:

Transmitted herewith are the following for the above-identified application:

1. Response to Restriction Requirement (10 pp.).

The fee has been calculated as shown below.

Claims	Claims After Amendment		Claims Previously Paid For	-	Percent Extra	Other Than Small Entity Rate	Fee	Additional Fee(s)
Total	20	-	20	-	0	x\$18.00	0	\$ 0
Indept.	3	-	3	-	0	x\$36.00	0	\$ 0
First Presentation of Multiple Dependent Claims:						+290.00	0	\$ 0
Total Fee:								\$ 0

☒ No additional Fee is required.☐ Please charge Deposit Account No. 09-0108 in the amount of: \$ _____

The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17, or credit overpayment to Deposit Account No. 09-0108. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

INCYTE CORPORATION

Date: October 29, 2003[Signature]

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Docket No.: PF-0169-2 CON

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: **Bandman et al.**

OFFICIAL

Title: **LUNG GROWTH FACTOR VARIANT**

Serial No.: **09/938,885**

Filing Date: **August 24, 2001**

Examiner: **Romeo, D.**

Group Art Unit: **1647**

Mail Stop: **Non-Fee Amendment**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT UNDER 35 U.S.C. 121

Sir:

This paper is responsive to the Restriction Requirement and Request for Election dated **September 29, 2003**, setting a **1-month** term for response. Prior to examination of the application, please amend the claims of the above-identified application as listed below.

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IN THE CLAIMS

This listing of the claims replaces all prior versions of the claims in the application.

Listing of the Claims

1. (Currently Amended) An isolated polypeptide ~~comprising an amino acid sequence~~ selected from the group consisting of:
 - a) a polypeptide comprising an amino acid sequence of SEQ ID NO:1,
 - b) a polypeptide comprising a naturally occurring polypeptide ~~comprising an amino acid sequence at least 90% identical to an amino acid sequence of SEQ ID NO:1,~~
 - c) a biologically active fragment of a polypeptide having an amino acid sequence of SEQ ID NO:1, and
 - d) an immunogenic fragment of a polypeptide having an amino acid sequence of SEQ ID NO:1.
2. (Currently Amended) An isolated polypeptide of claim 1 comprising an amino acid sequence ~~[[,]] having a sequence of SEQ ID NO:1.~~
3. (Original) An isolated polynucleotide encoding a polypeptide of claim 1.
4. (Original) A recombinant polynucleotide comprising a promoter sequence operably linked to a polynucleotide of claim 3.
5. (Original) A cell transformed with a recombinant polynucleotide of claim 4.
6. (Canceled)
7. (Original) A method for producing a polypeptide of claim 1, the method comprising:

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- a) culturing a cell under conditions suitable for expression of the polypeptide, wherein said cell is transformed with a recombinant polynucleotide, and said recombinant polynucleotide comprises a promoter sequence operably linked to a polynucleotide encoding the polypeptide of claim 1, and
- b) recovering the polypeptide so expressed.

8. (Original) An isolated antibody which specifically binds to a polypeptide of claim 1.

9. (Original) An isolated polynucleotide comprising a sequence selected from the group consisting of:

- a) a polynucleotide comprising a polynucleotide sequence of SEQ ID NO:2,
- b) a naturally occurring polynucleotide comprising a polynucleotide sequence at least 90% identical to a polynucleotide sequence of SEQ ID NO:2,
- c) a polynucleotide having a sequence complementary to a polynucleotide of a),
- d) a polynucleotide having a sequence complementary to a polynucleotide of b) and
- e) an RNA equivalent of a)-d).

10. (Original) An isolated polynucleotide comprising at least 60 contiguous nucleotides of a polynucleotide of claim 9.

11. (Original) A method for detecting a target polynucleotide in a sample, said target polynucleotide having a sequence of a polynucleotide of claim 9, the method comprising:

- a) hybridizing the sample with a probe comprising at least 20 contiguous nucleotides comprising a sequence complementary to said target polynucleotide in the sample, and which probe specifically hybridizes to said target polynucleotide, under conditions whereby a hybridization complex is formed between said probe and said target polynucleotide or fragments thereof, and
- b) detecting the presence or absence of said hybridization complex, and, optionally, if present, the amount thereof.

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12. (Original) A method of claim 11, wherein the probe comprises at least 60 contiguous nucleotides.

13. (Original) A method for detecting a target polynucleotide in a sample, said target polynucleotide having a sequence of a polynucleotide of claim 9, the method comprising:

- a) amplifying said target polynucleotide or fragment thereof using polymerase chain reaction amplification, and
- b) detecting the presence or absence of said amplified target polynucleotide or fragment thereof, and, optionally, if present, the amount thereof.

14. (Original) A composition comprising a polypeptide of claim 1 and a pharmaceutically acceptable excipient.

15. (Currently Amended) A composition of claim 14, wherein the polypeptide comprises has an amino acid sequence of SEQ ID NO:1.

16. (Canceled)

17. (Original) A method for screening a compound for effectiveness as an agonist of a polypeptide of claim 1, the method comprising:

- a) exposing a sample comprising a polypeptide of claim 1 to a compound, and
- b) detecting agonist activity in the sample.

18.-19. (Canceled)

20. (Original) A method for screening a compound for effectiveness as an antagonist of a polypeptide of claim 1, the method comprising:

- a) exposing a sample comprising a polypeptide of claim 1 to a compound, and
- b) detecting antagonist activity in the sample.

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21.-24. (Canceled)

25. (Original) A method for screening a compound for effectiveness in altering expression of a target polynucleotide, wherein said target polynucleotide comprises a polynucleotide sequence of SEQ ID NO:2, the method comprising:

- a) exposing a sample comprising the target polynucleotide to a compound, under conditions suitable for the expression of the target polynucleotide,
- b) detecting altered expression of the target polynucleotide, and
- c) comparing the expression of the target polynucleotide in the presence of varying amounts of the compound and in the absence of the compound.

26. (Original) A method for assessing toxicity of a test compound, said method comprising:

- a) treating a biological sample containing nucleic acids with the test compound;
- b) hybridizing the nucleic acids of the treated biological sample with a probe comprising at least 20 contiguous nucleotides of a polynucleotide of claim 9 under conditions whereby a specific hybridization complex is formed between said probe and a target polynucleotide in the biological sample, said target polynucleotide comprising a polynucleotide sequence of a polynucleotide of claim 9 or fragment thereof;
- c) quantifying the amount of hybridization complex; and
- d) comparing the amount of hybridization complex in the treated biological sample with the amount of hybridization complex in an untreated biological sample, wherein a difference in the amount of hybridization complex in the treated biological sample is indicative of toxicity of the test compound.

27.-42. (Canceled)

43. (Original) A microarray wherein at least one element of the microarray is a polynucleotide of claim 10.

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44. (Canceled)

45. (Original) An array comprising different nucleotide molecules affixed in distinct physical locations on a solid substrate, wherein at least one of said nucleotide molecules comprises a first oligonucleotide or polynucleotide sequence specifically hybridizable with at least 30 contiguous nucleotides of a target polynucleotide, said target polynucleotide having a sequence of claim 9.

46.-51. (Canceled)

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REMARKS

In the Restriction Requirement, the Examiner requested Applicants to elect one of the following inventions:

Group I (Claims 1, 2, 14, and 15) drawn to a polypeptide;

Group II (Claims 3-5, 7, 9, 10, 43, and 45) drawn to a polynucleotide;

Group III (Claim 8) drawn to an antibody;

Group IV (Claims 11, 12, 25, and 26) drawn to a measuring or testing process involving nucleic acid;

Group V (Claim 13) drawn to a method of preparing a nucleotide involving PCR;

Group VI (Claim 17) drawn to an indeterminate method of detecting an indeterminate agonist activity; and

Group VII (Claim 20) drawn to an indeterminate method of detecting an indeterminate antagonistic activity.

Applicants hereby elect, with traverse, to prosecute Group I, which includes and is drawn to Claims 1, 2, 14, and 15.

Applicants submit that the invention encompassed by the claims of Group II drawn to polynucleotides and of Group III drawn to antibodies, could be examined at the same time as the invention encompassed by the claims of Group I without undue burden on the Examiner. For example, a search of the prior art to determine the novelty of the polypeptides of Group I would provide information regarding the novelty of the polynucleotides of Group II and the antibodies of Group III.

Applicants submit that Claim 17 (Group VI) and Claim 20 (Group VII) are methods of using the polypeptides of Group I, which should be examined together with the polypeptides of Group I, per the Commissioner's Notice in the Official Gazette of March 26, 1996, entitled "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)" which sets forth the rules, upon allowance of product claims, for rejoinder of process claims covering the

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same scope of products. Furthermore, Applicants submit that Claims 11, 12, 25, and 26 (Group IV) and Claim 13 (Group V) are methods of using the polynucleotides of Group II, which should be examined together with the polynucleotides of Group II, per the Commissioner's Notice in the Official Gazette of March 26, 1996.

Applicants further traverse on the grounds that the Examiner could also examine the claims of Group II without undue burden, in view of the fact that they are related to, although of different scope from, claims already allowed in parent application U.S. Serial No. 08/760,745, now U.S. Patent No. 5,972,658. For the Examiner's convenience, those claims are as follows:

1. An isolated and purified polynucleotide sequence encoding the lung growth factor variant (LGVF) having the amino acid sequence of SEQ ID NO:1.
2. A hybridization probe comprising the polynucleotide sequence of claim 1.
3. An isolated and purified polynucleotide sequence comprising SEQ ID NO:2.
4. A polynucleotide sequence which is fully complementary to SEQ ID NO:2.
5. A hybridization probe comprising the polynucleotide sequence of claim 4.
6. An expression vector containing the polynucleotide sequence of claim 1.
7. A host cell line containing the expression vector of claim 6.
8. A method for producing a polypeptide comprising the amino acid sequence of SEQ ID NO:1, the method comprising the steps of:
 - a) culturing the host cell line of claim 7 under conditions suitable for the expression of the polypeptide; and
 - b) recovering the polypeptide from the host cell line culture.

Applicants additionally submit that in any case, there is minimal additional burden on the Examiner to examine the claims of Group II in addition to the claims of Group I, particularly in view of the additional burden on Applicants to file, prosecute and maintain yet additional applications in this family, and respectfully request that the Examiner consider doing so.

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Accordingly, because the search required to identify prior art relevant to the claims of Groups I, II, III, IV, V, VI, and VII would substantially overlap, Applicants respectfully submit that examination of Claims 1-5, 7-15, 17, 20, 25-26, 43, and 45 would pose no undue burden. Thus, Applicants request reconsideration and withdrawal of the Restriction Requirement and examination of Claims 1-5, 7-15, 17, 20, 25-26, 43, and 45. Applicants reserve the right to prosecute the subject matter of non-elected claims, or of any subject matter disclosed but not herein claimed, in a later continuation or divisional application.

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CONCLUSION

In light of the above amendments and remarks, Applicants submit that the present application is fully in condition for allowance. Early notice to that effect is earnestly solicited.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicants invite the Examiner to contact the undersigned at the number listed below.

Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. 09-0108.

Respectfully submitted,
INCYTE CORPORATION

Date: October 29, 2003

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